

Building an Integrated Laboratory System to Advance the Safety of Food and Animal Feed

EXECUTIVE SUMMARY OF YEAR FOUR PROGRESS REPORT

September 1, 2015 – August 31, 2016

The Association of Food and Drug Officials (AFDO), the Association of American Feed Control Officials (AAFCO), and the Association of Public Health Laboratories (APHL) continue to accomplish the goals of a 5-year Cooperative Agreement with FDA to support food and feed testing laboratories seeking to achieve or enhance accreditation to the ISO/IEC 17025:2005 standard. Improvement in the operations, efficiency and effectiveness of laboratories via accreditation to the ISO 17025 standard is foundational to building an Integrated Food Safety System (IFSS). This Executive Summary captures the successes achieved in Year 4 of the Cooperative Agreement. Workgroup involvement continues to be very robust, with over 100 individuals actively contributing. The activities listed below support all governmental food and feed laboratories pursuing ISO accreditation:

- Finalizing the Data Acceptance White Paper, and accompanying Glossary and Checklist. These tools are meant to assist laboratories and their customers in data review, particularly when testing informs a regulatory action.
- Releasing Guidance on Obtaining Defensible Samples (GOODSamples) available as a free download from the [AAFCO website](#). This document proposes systematic “fit for purpose/fit for decision” sampling based on Theory of Sampling to improve data quality and accuracy.
- Developing a National Plan for sustaining Laboratory Accreditation beyond FDA’s five-year Cooperative Agreement. The plan includes the benefits of accreditation for both the accredited laboratory and the customer, examples of successful use of data from accredited laboratories and strategies to sustain accreditation moving forward.
- Continuing development of the Governmental Food and Feed Laboratory Curriculum Framework, as well as drafting key performance indicators for the identified content areas. This framework identifies competencies and training necessary for food and feed laboratory professionals to participate in an integrated food safety system.
- Hosting the [Governmental Food and Feed Laboratories Accreditation Meeting](#) Feb 2-4, 2016 in Louisville, KY. The presentations, discussions and exercises provided training for laboratories pursuing ISO 17025 accreditation.
- Presenting a workshop on eLEXNET at the 2016 Public Health Informatics Conference entitled “eLEXNET: Integrating the Food Safety System.”
- Completing three state sampling pilots based on the GOODSamples recommendations, providing training to over 50 feed testing professionals.
- Holding six training workshops based on GOODSamples recommendations, providing training to 112 people.
- Developing and presenting ISO 17025 learning events, including workshops, live and archived webinars, a conference dedicated to laboratory accreditation, and on-demand courses. Webinars included:
 - A revised summary of the 2015 AOAC ALACC Guidelines (September 2015)

- An overview of the FDA/ORA Laboratory Accreditation Program and Requirements for ISO 17025 Accreditation (October 2015)
- Measurement of Uncertainty for Life Sciences Laboratories (December 2015)
- GOODSamples: Guidance on Obtaining Defensible Samples (March 2016)
- Document and Record Control (April 2016)
- Quality Policies and Objectives and Management Review (July 2016)
- Providing direct technical assistance to 10 state laboratories seeking accreditation without the benefit of FDA ISO program funding. Support included site visits, conference calls, review of quality manuals and methods, creation of record templates, internal audits, and evaluation of document control systems.
 - The Arizona Department of Health Services and the Nebraska Department of Agriculture Laboratory achieved ISO 17025 accreditation in late 2015. Arkansas Department of Health used APHL resources to expand its accreditation.
- Managing a [Food and Feed Laboratory Accreditation Discussion Board](#), an online forum for exchange of ideas on how best to achieve accreditation. Of the 94 participants, 86 are from 52 different state and local laboratories.
- Hosting a web-based repository of over 250 resources organized according to the ISO standard, including examples of best practices, standard operating procedures, worksheets, records and work plans.
- Facilitating laboratory collaboration with regulatory food programs to update the manufactured food regulatory program standards and sampling plans.
- Gathering feedback on eLEXNET improvements via the National Users Group and through demonstrations provided to APHL's Food and Feed Testing Subcommittee and at the Governmental Food and Feed Laboratories Accreditation Meeting.
- Maintaining a [Subject Matter Expert \(SME\) Registry](#) hosted on the AFDO website which includes food and feed laboratory professionals. As of August 31, 2016, the registry includes 45 Food Laboratory SMEs.
- Maintaining AFDO's [web-based information portal](#) to expand data collection and integrate both public and protected tools for effective sharing of resources for improving the food/feed safety systems with respect to laboratory accreditation.
- Leading a Laboratory Managers Steering Committee, which collaborates closely with the Manufactured Foods Retail Programs Alliance in order to promote integration between regulatory and laboratory partners.
- Providing access to [AAFCO's accredited PT program](#) that meets ISO/IEC accreditation requirements for FSMA critical tests in feed, food and pet food and expanding the Pet Food Program, Mycotoxin Contaminants Program, Minerals Program and Veterinary Drug and Drug Residue Program.
- Maintaining a current a [list of relevant proficiency testing providers](#) for food and feed laboratories.

The collaborative efforts of APHL, AFDO and AAFCO continue to facilitate ISO 17025 accreditation of governmental food and feed testing laboratories. The resources provided through this cooperative agreement will carry on long after the 5-year funding period, assisting laboratories as they attain or maintain ISO accreditation. The cumulative impact of Association efforts will be realized in an increase in the overall number of ISO 17025 accredited governmental food and feed testing laboratories contributing to a fully Integrated Food Safety System.